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ORIGINAL ARTICLE

# Safe and effective use of conscious sedation for defibrillation threshold testing during ICD implantation

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**KEYWORDS**

Conscious sedation;
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**Abstract** *Background:* Over a period of years general anesthesia has been a standard anesthetic technique for defibrillation threshold (DFT) testing at the time of implant. DFT testing without general anesthesia cover has gained limited acceptance. Use of local anesthesia combined with deep sedation for DFT testing might facilitate and simplify these procedures by reducing the procedural time, staff time, avoiding inefficient service in organizing anesthetic cover; thereby improving patient compliance.

*Objective:* The objective of this study was to evaluate feasibility, safety and efficacy of conscious sedation for DFT testing during Implantable cardioverter defibrillators (ICD) implantation.

*Method:* Data of 87 non-selected patients who achieved adequate sedation with titrated doses of midazolam and pethidine were analyzed retrospectively. These medications were administered by a circulating nurse under the supervision of the implanting physicians. All hemodynamic measures, treatment and complications were monitored and recorded throughout the procedure.

*Results:* A retrospective analysis of data from 87 patients who underwent ICD implantation and DFT testing under conscious sedation at our center was reported. The mean dose of midazolam and pethidine administered was 4.9 ± 1.8 and 47.7 ± 20 mg, respectively. During the period of conscious sedation, no patient depicted episode of sustained apnea. No major complication or mortality was reported.

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*Conclusion:* Use of conscious sedation as an alternative to the use of general anesthesia for DFT testing during ICD implantation is found to be feasible, safe and effective, with an added advantage of reduced procedural time and improved patient compliance.



## 1. Introduction

Implantable cardioverter defibrillators (ICDs) were first introduced in early 1980s (Curtis, 2008). ICDs offer a significant opportunity to decrease procedural morbidity and medical costs in the care of patients with life-threatening ventricular arrhythmias (who otherwise would have required a sternotomy or thoracotomy for device insertion) (Bardy et al., 1993). To ensure that the system has an acceptable defibrillation threshold safety margin at the time of implant, the standard of care that has long been accepted is the defibrillation threshold (DFT) testing (Mainigi and Callansm, 2006). DFT testing has traditionally been performed under general anesthesia. Despite the widespread use of general anesthesia for this procedure, organizing anesthetic cover for the procedure can sometimes be a challenging experience for the cardiologist. In addition, patients with poor LVEF are prone to cardiovascular complication under general anesthesia (Singh et al., 2004).

The list of challenges using GA include procedural delay, cardiovascular complications during treatment, patient apprehension and incompatibility, waste of staff time and an inefficient service (Foster, 1995; Eastman et al., 1995). Direct hemodynamic and electrophysiological effects of general anesthetics on heart and on defibrillation energy requirement have been reported. Animal studies have shown an increase in defibrillation energy requirement in the presence of vasopressor (Knight et al., 1999). To overcome these challenges, newer techniques have been developed.

Physicians in a variety of specialties have experience in providing safe sedation for unpleasant procedures. In cardiology, wide spread use of transesophageal echocardiography has led to familiarity with administration of sedative agents (Working Party Report, 1993; Saltissi et al., 1994). Moreover, an increased cost and difficulties in arranging anesthetic cover have influenced the cardiologist's inclination towards the use of sedative agents.

It is now possible to place the ICDs under local anesthesia in electrophysiology laboratories with techniques similar to those used for the insertion of permanent pacemakers. Despite the fact that this technique has a similar safety and reliability profile, and the cardiorespiratory functions remain uncompromised, DFT during implantation of ICD without general anesthesia has gained limited acceptance (Singh et al., 2004; Tung and Bajaj, 1995). In order to identify the successful applicability of the alternative techniques for DFT testing at the time of implantation of ICD in the absence of general anesthesia, this study was conducted with the objective of evaluating the feasibility, safety and efficacy of conscious sedation for DFT testing during ICD implantation (without anesthesia cover).

## 2. Method

### 2.1. Data collection

Data from 250 patients who underwent ICD implantation and defibrillation threshold testing under conscious sedation at our center between March 2008 and November 2009 were compiled. Data from 130 patients were randomly selected for analysis. Forty three patients were excluded from analysis due to insufficient data. Written informed consent was obtained from all the patients. All the baseline characteristics of the patients were thoroughly reviewed.

### 2.2. Data extraction and assessment parameters

Data relating to patient characteristics, procedure, and safety and efficacy outcomes were analyzed and the results were interpreted.

#### 2.2.1. Patient characteristics

Demographic characteristics of the patients pertaining to age, gender, height and weight were recorded. BMI was calculated from the available information to assess obesity. Primary underlying cardiac conditions such as coronary artery disease, dilated cardiomyopathy, hypertrophic cardiomyopathy, congenital abnormalities and valvular involvement were looked for. A thorough medical history including history of congestive heart failure, hypertension, diabetes mellitus, clinical ventricular arrhythmia and chronic obstructive pulmonary disease was recorded. History of medications such as digoxin, beta-blockers, calcium channel blockers and angiotensine converting enzyme inhibitor (ACEI) or angiotensine receptor blockers (ARBs) was also incorporated. Creatinine values were recorded and classified as normal and abnormal. Quantitative left ventricular ejection fraction for each patient was recorded.

#### 2.2.2. Procedure

The implantation procedure was conducted in a clean and sterilized procedure room equipped for emergency intubation and ventilation. All procedures were devoid of anesthetic cover. Sedative drugs namely midazolam and pethidine were ordered by the implantation physician and administered by the circulating nurses in titrated doses as needed to achieve adequate sedation. The effectiveness of sedation was closely monitored by observing the patient's state of consciousness, response to interrogation or other stimuli, respiration pattern, eyelash reflex, oxygen saturation, blood pressure and cardiac rhythm. Continuous pulse oxymetry and cyclic non-invasive blood pressure were monitored throughout the procedure. Anexate (flumazenil) availability was mandatory in the procedure room as an antidote for midazolam adverse effect. Defibrillation threshold testing was performed once in each patient unless the first attempt failed.

The procedural time was recorded. Dose of midazolam and pethidine administered to the patients was tabulated.

#### 2.2.3. Safety and efficacy assessment

Side effects such as hypotension, hypoxia and apnea were recorded. Supportive measures adapted such as inotropic agents, oxygen supplementation, antidote requirement and intubation were recorded. Complications like bleeding requiring transfusion, major vessel tear or perforation, pericardial effusion or

tamponade requiring drainage, pericardial effusion without tamponade, infection of the new device within the first 30 days, hematoma requiring drainage, ventricular arrhythmia requiring DC shock, and other technical complications were assessed. Mortality was also recorded.

## 3. Results

### 3.1. Patient characteristics

Data of 87 patients were analyzed retrospectively. The mean age was 54.66 year (range: 17–76). Eighty two percent of the subjects was male. The mean height and weight were 167.74 cm and 75.23 kg, respectively. Forty three percent of study population was overweight. Majority of the patients (70%) were diagnosed to have coronary artery disease. Dilated cardiomyopathy and valvular diseases were accounted for less than 25%. Around 6% of patients had no reported structural heart disease. The mean quantitative left ventricular ejection fraction was 25.8% (range: 10–60). The medical history of the patients depicted congestive heart failure (CHF) (63%), hypertension (32%), diabetes mellitus (26%), clinical ventricular arrhythmia (CVA) (2%) and chronic obstructive pulmonary disease (COPD) (8%). A greater proportion of the subjects received ACEI/ARBs (87%) and beta-blockers (76%); while a relatively small proportion received digoxin (27%) and calcium channel blockers (6%). Abnormal creatinine values were recorded in 40% of the subjects Table 1.

### 3.2. Conscious sedation execution

The procedure was conducted once in each subject. The mean procedural time was 52 min (range: 30–110 min). The mean concentration of midazolam and pethidine administered was 4.9 ± 1.8 and 47.7 ± 20.0 mg, respectively Table 2. The most frequently used dose of midazolam was 4 mg accounted for (29%) and 50 mg of pethidine (53%).

### 3.3. Safety and efficacy outcomes

Adequate sedation was achieved in all the subjects. No major complications or mortalities were observed. Though side effects such as hypotension and hypoxia were recorded in 5

**Table 1** Patient characteristics.

| Characteristics | Frequency [Mean(range)/*N*(%)] |
|---|---|
| *Number of patients* | 87 |
| Demographic data | |
| Age | 54.66 years (17–76 years) |
| Gender | |
| Male | 71 (82%) |
| Female | 16 (18%) |
| Height | 167.74 cm (151–188 cm) |
| Weight | 75.23 kg (51–110 kg) |
| BMI | 26.79 (18.11–42.44) |
| Under weight | 2 (2%) |
| Normal | 30 (35%) |
| Over weight | 37 (43%) |
| Obese | 18 (20%) |
| *Primary underlying cardiac disease* | 82 (94%) |
| Coronary artery disease | 60 (70%) |
| Dilated cardiomyopathy | 18 (20%) |
| Valvular diseases | 4 (4%) |
| None | 5 (6%) |
| LVEF | 25.80% (10–60%) |
| *Medical history* | |
| Congestive heart failure | 55 (63%) |
| Hypertension | 28 (32%) |
| Diabetes mellitus | 23 (26%) |
| Clinical ventricular arrhythmia | 2 (2%) |
| Chronic obstructive pulmonary disease | 7 (8%) |
| *Medications* | |
| Digoxin | 24 (27%) |
| Beta-blockers | 66 (76%) |
| Calcium channel blockers | 5 (6%) |
| ACEI/ARBs | 76 (87%) |
| Abnormal creatinine values | 35 (40%) |

ACEI, angiotensin converting enzyme inhibitor; ARBs, angiotensin receptor blockers; LVEF, left ventricular ejection fraction.

**Table 2** Conscious sedation induction.

| | Frequency (%) |
|---|---|
| *Procedural time in minutes* | |
| 30–50 | 45 (52) |
| 51–70 | 38 (44) |
| 71–90 | 2 (2) |
| 91–110 | 2 (2) |
| *Midazolam dose in mg* | |
| 2 | 11 (13) |
| 3 | 6 (7) |
| 4 | 25 (29) |
| 5 | 14 (16) |
| 6 | 14 (16) |
| 7 | 4 (4) |
| 8 | 13 (15) |
| *Pethidine dose in mg* | |
| 25 | 27 (31) |
| 50 | 46 (53) |
| 75 | 9 (10) |
| 100 | 5 (6) |

**Table 3** Safety and efficacy outcomes.

| Outcome | Frequency (%) |
|---|---|
| Sedation achieved | 87 (100) |
| *Side effects* | |
| Hypoxia | 3 (3) |
| Hypotension | 5 (6) |
| Apnea | 0 (0) |
| *Supportive measures* | |
| Inotropic support | 4 (5) |
| Oxygen supplementation | 3 (3) |
| Antidote | 1 (1) |
| Intubation | 0 (0) |
| Major complications | 0 (0) |
| Death | 0 (0) |

(6%) and 3 (3%) subjects, respectively, apnea was not reported. 7 out of 8 side effects were observed in patient group receiving 50 mg pethidine. Inotropic support, oxygen supplementation and antidote were required in 4 (5%), 3 (3%), and 1 (1%) subjects, respectively. No patient required intubation Table 3.

## 4. Discussion

The developments of reliable trans-venous leads systems and down-sized generators have greatly facilitated the placement of ICDs (Natale et al., 1996). However, optimal anesthetic and surgical techniques for the implantation of these devices remain controversial (Foster, 1995; Eastman et al., 1995).

Review of the recent published reports reveals that the majority of electrophysiologists continue to place ICDs in operating rooms under general anesthesia (Wever et al., 1995; Zipes and Roberts, 1995; Villacastín et al., 1996). Arguing that intravenous sedation fails to ensure adequate ventilation in critically ill patients and that ventilator difficulties may contribute to hemodynamic deterioration, Epstein and Kay (1994) advocated routine elective endotracheal intubation and mechanical ventilation for the placement of ICDs.

Whether the general anesthesia or conscious sedation influences the defibrillation threshold remains a matter of debate. Moerman et al. (1998) have shown that both types of anesthesia (local or general) did not influence the threshold of cardioversion.

Physicians in a variety of specialties have experienced in providing safe sedation for unpleasant procedures. In cardiology the wide spread use of transesophageal echocardiography has led to familiarity with administration of sedative agents (Saltissi et al., 1994). Moreover, an increased cost and difficulties in arranging anesthetic cover have influenced the cardiologist's inclination towards the use of sedative agents.

Many sedative agents have been shown to be safe and effective for achieving their purpose with minimal limitation. The choices are however open for the physicians depending up on their experience and comfort. Canessa et al. (1991) compared thiopental, propofol, etomidate and midazolam and found midazolam to be longer acting. Midazolam is used as a sedative agent in our study considering this characteristic as one of its advantages over other agents. Thiopental and propofol were associated with hypotension and etomidate was associated with pain on injection on myoclonus (Canessa et al., 1991). Gale et al. (1993) found that the time of awakening with midazolam was triple of that with propofol and methohexital. Goldner et al. (1998) also suggested the use of morphin and midazolam in their study. In one report, propofol resulted in hypotension and significant decrease in heart rate and apnea which required mechanical ventilation, but it has been shown to be good alternative to general anesthesia for ICD implantation (Kick et al., 1996; Hara et al., 1999). On the contrary, our analysis reported that no patient developed apnea when they were sedated with the titrated dose of midazolam and pethidine. Raipancholia et al. (2001) used pethidine to augment sedation by midazolam in which the requirement of pethidine varied inversely with age, with no patients requiring intubation or hospital admission. Similar observation was noted in our study, wherein no patient required assisted ventilation by face mask or endotracheal intubation. However, 7 out of 8 of the side effects observed in our study were observed in patients administered with 50 mg pethidine.

Recall of shocks has not been addressed widely in previous studies. In one study including 149 patients who underwent external cardioversion, only five patients found it very unpleasant, but all patients had total amnesia with regards to the procedure with midazolam sedation (Dellinger et al., 1988). Valtonen et al. reported the experience of 5 patients sedated twice with propofol and thiopentone for cardioversion. They assessed the anesthesia procedure with propofol as being more pleasant (Valtonen et al., 1988) similarly, in our study; all patients were unable to recall the defibrillation testing.

One of the limitations of the current study is the cost which was not targeted, but few reports have clearly shown significant reduction in cost when a cardiologist administer sedation without anesthesia cover (Botkin et al., 2003). However, the technique did not require an anesthetist as the agents were administered by circulating nurses under the supervision of the implanting physician, hence the direct cost to staff reduced.

## 5. Conclusion

Use of conscious sedation (intravenous midazolam and pethidine) for DFT testing during ICD implantation is a safe and effective alternative to general anesthetics in a well-equipped electrophysiology laboratory in the hands of well-trained health care personnel and experienced cardiologist.

## Conflict of interest

None declared.

## References

Bardy, G.H., Hofer, B., Johnson, G., et al., 1993. Implantable transvenous cardioverter-defibrillators. Circulation 87 (4), 1152–1168.

Botkin, S.B., Dhanekula, L.S., Olshansky, B., 2003. Outpatient cardioversion of atrial arrhythmias: efficacy, safety, and costs. Am. Heart J. 145 (2), 233–238.

Canessa, R., Lema, G., Urzúa, J., et al., 1991. Anesthesia for elective cardioversion: a comparison of four anesthetic agents. J. Cardiothorac. Vasc. Anesth. 5, 566–568.

Curtis, A.B., 2008. Defibrillation threshold testing in implantable cardioverter-defibrillators: might less be more than enough? J. Am. Coll. Cardiol. 52 (7), 557–560.

Dellinger, A., Marchand, A., Zoheir, F., et al., 1988. Comparison of etomidate and thiopental for the anesthesia in cardioversion. Ann. Fr. Anesth. Reanim. 7 (2), 128–131.

Eastman, D.P., Selle, J.G., Reames Sr., M.K., 1995. Technique for subpectoral implantation of cardioverter defibrillators. J. Am. Coll. Surg. 181 (5), 475–476.

Epstein, A.E., Kay, G.N., 1994. Implantation of cardioverter-defibrillators in the electrophysiology laboratory. In: Singer, I. (Ed.), Implantable Cardioverter-Defibrillator. Futura, Armonk (NY), pp. 357–364.

Foster, A.H., 1995. Technique for implantation of cardioverter defibrillators in the subpectoral position. Ann. Thorac. Surg. 59 (3), 764–767.

Gale, D.W., Grissom, T.E., Mirenda, J.V., 1993. Titration of intravenous anesthetics for cardioversion: a comparison of propofol, methohexital, and midazolam. Crit. Care Med. 21, 1509–1513.

Goldner, B.G., Baker, J., Accordino, A., et al., 1998. Electrical cardioversion of atrial fibrillation or flutter with conscious sedation in the age of cost containment. Am. Heart J. 136, 961–964.

Hara, M., Uchida, O., Kuro, M., et al., 1999. Anesthetic management for implantation of implantable cardioverter-defibrillators. Masui 48 (7), 747–752.

Kick, O., Böhrer, H., Motsch, J., et al., 1996. Etomidate versus propofol for anesthesia in ambulatory cardioversion. Anasthesiol Intensivmed Notfallmed Schmerzther 31 (5), 288–292.

Knight, B.P., Pelosi, F., Flemming, M., et al., 1999. Effect of general anesthesia on the defibrillation energy requirement in patients undergoing defibrillator implantation. J. Interv. Card. Electrophysiol. 3 (4), 325–328.

Mainigi, S.K., Callansm, D.J., 2006. How to manage the patient with a high defibrillation threshold. Heart Rhythm 3 (4), 492–495.

Moerman, A., Herregods, L., Tavernier, R., et al., 1998. Influence of anaesthesia on defibrillation threshold. Anaesthesia 53 (12), 1156–1159.

Natale, A., Kearney, M.M., Brandon, M.J., et al., 1996. Safety of nurse-administered deep sedation for defibrillator implantation in the electrophysiology laboratory. J. Cardiovasc. Electrophysiol. 7, 301–306.

Raipancholia, R., Sentinella, L., Lynch, M., 2001. Role of conscious sedation for external cardioversion. Heart 86, 571–572.

Saltissi, S., de Belder, M.A., Nihoyannopoulos, P., 1994. Setting up a transoesophageal echocardiography service. Br. Heart J. 71 (Suppl. 4), 15–19.

Singh, V.P., Shahi, B.N., Dhall, A., et al., 2004. Conscious sedation as an anaesthetic technique in patients undergoing nonthoracotomy placement of automatic implantable cardioverter defibrillator: an initial experience. Ann. Card. Anaesth. 7 (2), 149–154.

Tung, R.T., Bajaj, A.K., 1995. Safety of implantation of a cardioverter-defibrillator without general anesthesia in an electrophysiology laboratory. Am J. Cardiol. 75 (14), 908–912.

Valtonen, M., Kanto, J., Klossner, J., 1988. Anaesthesia for cardioversion: a comparison of propofol and thiopentone. Can. J. Anaesth. 35 (5), 479–483.

Villacastín, J., Almendral, J., Arenal, A., et al., 1996. Incidence and clinical significance of multiple consecutive, appropriate high-energy discharges in patients with implanted cardioverter-defibrillators. Circulation 93, 753–762.

Wever, E.F., Hauer, R.N., van Capelle, F.L., et al., 1995. Randomized study of implantable defibrillator as a first-choice therapy versus conventional strategy in postinfarct sudden death survivors. Circulation 91, 2195–2203.

Working Party Report, 1993. Guidelines for Sedation by Nonanaesthetists. Royal College of Surgeons of England, London.

Zipes, D.P., Roberts, D., 1995. Results of the international study of the implantable pacemaker cardioverter-defibrillator: comparison of epicardial and endocardial lead systems. Circulation 92, 59–65.